Public Health Service

DEPARTMENT OF HEALTH AND HUMAN SERVICES

T1990M

Food and Drug Administration
555 Winderley Place, Suite 200
Maitland, Florida 32751

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-98-67

August 10, 1998

Elliott R. Mandell, President
Rocap, Div. of Sabratek
1629 Prime Court #300
Orlando, Florida 32809

Dear Mr. Mandell:

We are writing to you because on June 25 through July 9, 1998 FDA Investigator R. Kevin Vogel collected information that revealed serious regulatory problems involving sterile saline and heparin intravenous flush syringes (III) which are manufactured and distributed by your firm.

Under the Federal Food, Drug, and Cosmetic Act (The Act), these products are considered to be medical devices because they are used to treat a medical condition or to affect the structure or function of the body. The law requires that manufacturers of medical devices conform with the requirements of the Quality System (QS) regulation as specified in Title 21, Code of Federal Regulations (CFR), Part 820. The 1978 Good Manufacturing Practice (GMP) for Medical Devices regulation was superseded on June 1, 1997, by the Quality Systems regulation, which incorporates the device GMP.

The inspection revealed that the devices are adulterated within the meaning of section 501(h) of the Act, in that the methods used in, or the facilities or controls used for the manufacture, processing, packing, storage or distribution are not in conformance with the requirements of the Quality System (QS) regulation. These violations include, but are not limited to the following:

- Failure to identify complaints and implement adequate corrective action required to correct and prevent the recurrence of non-conforming product, e.g., no corrective or preventive action taken in response to confirmed reports of particulate matter found in in-process rejects and finished product, sterility failures related to closure integrity, and recurring complaints of blunt cannula tips falling off.

- Failure to conduct finished product testing prior to release of product for distribution to ensure each production run or lot meets acceptance criteria, e.g., no finished product testing for devices from September 4, 1997 to November 3, 1997 and finished product testing is not conducted routinely to assure release criteria are met prior to distribution.

- Failure to establish and document purchasing controls that verify component suppliers ability to meet specified requirements, e.g., no verification that incoming components meet specifications, except for receipt of a certificate of conformance; no evaluation of incoming syringes and closures after the first 5 lots, at 6 months and annually thereafter; no inspection for product dimension or particulates; no documentation of component supplier evaluations or audits; and agreements with suppliers are not always obtained.

- Failure to follow your own written production and process control procedures for monitoring and controlling process parameters with respect to sterility failures and media fills, e.g., investigations of sterility failures are not conducted in a timely manner; data from Rodac plate samples taken on December 20, 1997 were not reviewed and compared with findings revealed during failure investigations conducted in November 1997 and May 1998, which revealed the same bacteria found in the gown room near the sink; and media fill procedures are not followed, or adequately documented to assure that all manufacturing criteria and specifications are met.

- Failure to establish and maintain adequate environmental monitoring and controls, e.g., no sampling of personnel gowns and gloves; no action taken when bacterial counts from Rodac plates taken under hoods exceed your own SOP and alert limits; no monitoring of environmental trends on a routine basis; inadequate documentation of all procedures conducted during air sampling for particulates; no documentation showing resolution of deviations in pressure between the clean room and the gowning and prep room, as measured by the Magnehelic Gauges on numerous dates in November and December 1997, and January, February, March, April and June of 1998.

- Failure to assure that stability testing is adequate to support assignment of a one year expiration date, e.g., stability studies for all container/closure systems are incomplete; sodium chloride in the NS 1/3 product was found to be out of specification, but no action was taken nor was the deviation documented on a timely basis; and a batch record for Heparin 10 unit/ml (1ml in a 3 ml syringe) for accelerated stability testing was not available.

You should know that these are serious violations of the law that may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of the product, or assessing civil money penalties. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the Inspectional Observations (FDA 483), issued to you at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. Also, other Federal agencies are informed about the warning letters we issue, such as this one, so that they may consider this information when awarding government contracts.

It is necessary for you to take action on this matter. Please notify this office in writing within 15 working days of receipt of this letter, of the steps you are taking to prevent recurrence of these violations. If you need more time, let us know why and when you expect to complete your corrections. We note that FDA 483, Item #5 was reported corrected and verified by the investigator. Please direct your response to Timothy J. Couzins, Compliance Officer, Food & Drug Administration, Florida District, 555 Winderley Place, Suite 200, Orlando, Florida 32751.

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter pertains only to the requirements for the conformance of your devices with the Quality System Regulations and does not necessarily address other obligations you have under the law, e.g., your 510(k) premarket submission currently pending in the Center for Devices and Radiological Health (CDRH) has not been cleared permitting commercial distribution of your products. Any further distribution of these products is at your own risk. You may obtain general information about all of the FDA requirements for manufacturers of medical devices by contacting this office or through the Internet at http://www.fda.gov.

If you have more specific questions about the Quality System Regulation and how it affects your particular devices, or about the content of this letter, please contact Tim Couzins at (407) 475-4728.

Sincerely,

Douglas D. Tolen
Director, Florida District